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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,173	01/14/2002	Michela Seveso	9701-11	5272
20792 7590 12/22/2010 MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627				
EXAMINER				
ANGELL, JON E				
ART UNIT		PAPER NUMBER		
1635				
MAIL DATE		DELIVERY MODE		
12/22/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/743,173

Applicant(s)

SEVESO ET AL.

Examiner

J. E. ANGELL

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1.44, 46-52 and 55-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1.44, 46-52 and 55-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date 10/27/10
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/27/2010 has been entered.

Claims 1, 44, 46-52, 55-65 are currently pending in the application and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 10/27/2010 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 44, 46-51, 55, 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO99/01579 (Teng et al., of record) for the reasons of record.
2. Claims 1 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO99/01579 (Teng et al.) in view of GB2319773A (Lewin et al., of record) for the reasons of record.
3. Claims 57, 58, 63, 64, 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO99/01579 (Teng et al.) in view of Akhtar (J. Drug Targeting 1998, of record) for the reasons of record.
4. Claims 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO99/01579 (Teng et al.) in view of Akhtar (J. Drug Targeting 1998, of record) and Akhtar et al. (Int. J. Pharmaceutics, 1997; or record) for the reasons of record.
5. Claims 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO99/01579 (Teng et al., see above) in view of Nakashima et al. (J. Pharm. Sci., 1995) for the reasons of record.

Response to Arguments

6. Applicant's arguments filed 10/27/2010 have been fully considered but they are not persuasive.
7. Applicant argues that Teng et al. disclose only a single formulation containing a C10 fatty acid (FA) as the only enhancer (at a concentration of 1% which is 51.5mM) which provided 5% absorption. Applicant notes that Teng also discloses other formulations that comprise multiple enhancers with higher concentrations of FAs which produced better results. Applicant asserts that Teng teaches that a single enhancer by itself is least effective and that increasing amounts of FAs improved results. Applicant asserts that Teng does not provide motivation to use a CA FA as the only enhancer.
8. This is not persuasive because Teng et al. specifically teach using a C10 as the only enhancer (page 46) as acknowledged by Applicant.
9. Applicant also argues that Teng demonstrates that decreasing the ration of enhancer to nucleic acid (NA) leads to decreased bioavailability, which represents a true teaching away. Applicant asserts that the lowest concentration of C10 alone exemplified by Teng is 1% (51.5mM) which is about 4 times higher than the high range limitation of the claim.
10. This is not persuasive because although the single C10 enhancer exemplified by Teng is approximately four times higher concentration than is now claimed, this does not equate to a teaching away from using a lower concentration. A true teaching away would indicate that using the C10 at lower concentrations would result in ineffective delivery. In other words, a teaching away would lead one of ordinary skill in the art to believe that using concentrations within the claimed range would result in a failure to deliver the NA and thus should not be used. This is not

the case here where one of ordinary skill in the art would expect that the use of any amount of enhancer would still result in effective delivery.

The Applicant argues that the other references cited fail to make up for the deficiencies of Teng et al.

11. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

12. Furthermore, Applicant is respectfully reminded that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Therefore, Applicant's arguments are not persuasive.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. ANGELL whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 7:00 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Heather Calamita can be reached on 571-272-2876. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. ANGELL/
Primary Examiner, Art Unit 1635